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DOI: https://doi.org/10.1111/jcpe.12665

Clinical and radiographic intra-subject comparison of implants placed with or without guided bone regeneration: 15-year results

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Key words: dental implant, bone regeneration, bone augmentation, GBR, bone substitute, graft, membrane, clinical, human, long term, bone, mucosa, soft tissue, cone beam computed tomography, CBCT, radiology

Running title: 15-year follow-up after GBR vs. no GBR

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Abstract

Aim: To test whether implants placed with simultaneous guided bone regeneration (GBR) differ from implants placed without GBR regarding survival rate, interproximal marginal bone level (MBL), and dimensions of buccal bone and mucosa.

Material & Methods: Twenty-three patients treated 15 years earlier were included. Machined implants had been inserted following one of the two procedures: (1) with simultaneous GBR, which involved grafting with particulate deproteinized bovine bone mineral (DBBM), autogenous bone (AB) or a mixture of the two and defect covering with a native collagen membrane (CM), (GBR group) and (2) standard implant placement without GBR (control group). One GBR and one control implant in each patient were selected for analysis. At 15 years, the dimensions of buccal bone and mucosa were measured with cone beam computed tomography. The interproximal MBL was evaluated at 5 and 15 years on periapical radiographs.

Results: The 15-year survival rate amounted to 95.6% for GBR implants and to 94.1% for control implants. At 15 years, interproximal MBL measured 1.44±0.84 mm for the GBR group and 1.69±0.84 mm for the control group. From the 5- to the 15-year examination, the loss of interproximal MBL reached 0.23±0.70 mm for the GBR group and 0.28±0.63 mm for the control group. At 15 years, buccal MBL measured 1.98±0.98 mm for GBR implants and 2.19±1.29 mm for control implants. None of these values reached statistical significant differences between the groups. In cases in which GBR involved grafting with DBBM, GBR implants achieved approximately 0.3-0.4 mm higher mean values in buccal bone dimensions and mucosal level in comparison to control implants. In contrast, when GBR was performed by grafting with AB without DBBM, implants rendered less favorable results in buccal bone and mucosa dimensions than the control implants.

Conclusions: Implants placed with simultaneous GBR by using particulate DBBM and/or AB in combination with CM did not significantly differ from implants completely placed into pristine bone with respect to 15-year implant survival, interproximal bone levels, and dimensions of buccal bone and mucosa. The machined-surface implants placed both into native bone and sites augmented by GBR exhibited stable interproximal bone levels.

Clinical relevance

Scientific rationale: Even though guided bone regeneration is the most widely used method applied to augment bone in localized alveolar defects, there is scarce clinical evidence comparing the long-term results of implants placed with guided bone regeneration and those placed into pristine bone.

Principal findings: Implants placed with simultaneous guided bone regeneration by using particulate deproteinized bovine bone mineral and/or autogenous bone in combination with collagen membrane did not differ from implants completely placed into pristine bone with respect to 15-year implant survival, interproximal bone levels, and dimensions of buccal bone and mucosa.

Practical implications: Within the limitation of this study, the presence of peri-implant defects treated with guided bone regeneration does not appear to influence the long-term clinical performance of dental implants. The stability of the hard tissue augmented by using different biomaterials needs to be further investigated.

Introduction

Today, guided bone regeneration (GBR) is the most widely used and best-documented method applied to augment bone in localized alveolar defects (Benic & Hammerle 2014). There is a large body of short-term clinical evidence documenting that survival rates of dental implants placed simultaneously with, or after GBR are similar to survival rates of implants placed into native bone (Donos et al. 2008, Merli et al. 2016, Sanz-Sanchez et al. 2015, Hammerle et al. 2002, Jensen & Terheyden 2009). Most studies with internal controls found implant survival rates for a period up to 5 years ranging from 95 to 100% at both augmented and control sites (Benic et al. 2009, Mayfield et al. 1998, Zitzmann et al. 2001, Zumstein et al. 2012). Currently, there is scarce clinical evidence comparing the long-term results of implants placed with GBR and those placed into pristine bone. A recent clinical study assessed the survival rates of implants either placed with simultaneous with GBR or placed into native bone after a mean observation period of 12.5 years (Jung et al. 2013). It was found that the implant survival rates for the GBR and the control groups reached 93% and 95%, respectively.

With regards to the level of the interproximal marginal bone, the analysis of periapical radiographs within previous controlled studies did not reveal any difference between implants placed into augmented sites and those placed into native bone (Benic et al. 2009, Jung et al. 2013, Mayfield et al. 1998, Zumstein et al. 2012). The criticism of studies involving two-dimensional radiographs is the fact that outcome of GBR is assessed by measuring the interproximal bone level knowing that bone augmentation is most often performed at the buccal aspect of implants.

Therefore, the primary aim of the present intra-subject controlled study was to test whether implants placed simultaneously with GBR differ from implants completely placed into pristine bone regarding the 15-year interproximal and buccal marginal bone levels. In addition, the change in interproximal marginal bone level from 5 to 15 years, the 15-year mucosal level and the periodontal parameters were assessed.

Materials and methods

This study was designed as a 15-year clinical examination with intra-subject comparison of implants placed with and without GBR. The study was performed at the Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine, University of Zurich, Switzerland. The trial was approved by the local ethical committee (reference code KEK-ZH 2013-0036; Kantonale Ethik-Kommission, Zurich, Switzerland).

Thirty-two patients were included in the study who had received implants placed with simultaneous GBR (test group) and standard implant placement without bone augmentation (control group), and who had been examined 5 years after implant placement. The treatment procedures and the 5-year assessment were described in detail in a previous publication (Benic et al. 2009). Written informed consent was obtained from all the patients prior to the examination.

Treatment procedures

Depending on the quantity of bone, implants were placed following one of the following two procedures:

- *GBR:* With simultaneous GBR for the treatment of bone defects including dehiscences and infrabony defects. The GBR procedure involved grafting with a particulate deproteinized bovine bone mineral (DBBM) (Geistlich Bio-Oss® spongiosa granules, Geistlich Pharma AG, Wolhusen, Switzerland), autogenous bone harvested from the site of surgery or a mixture of the two. The site was covered with a native bilayer collagen membrane (Geistlich Bio-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland).
- *Control:* Standard implant placement executed in situations with bone volume sufficient for complete coverage of the endosseous implant surface.

All implants exhibited a machined endosseous surface (Brånemark System, Nobel Biocare, Kloten, Switzerland). The placement of implants was performed either as type 2, type 3, or type 4 procedure (Hammerle et al. 2004). The implants were primarily covered for submerged healing and loaded after a minimum healing time of 6 months. There was one exception, where healing was obtained with the implant in the transmucosal position and prosthetic loading 3 weeks after implant placement. This implant was lost after 4 months and, therefore, not included in the clinical and radiographic analyses.

Follow-up examination

The 5-year examination procedure was described in detail in a previous publication (Benic et al. 2009). Fifteen years after implant placement, one investigator, who was unaware of the specific treatment modality, examined the patients. One test and one control implant from each patient were selected for analysis. In each patient, the two study implants were located either in the anterior or in the posterior regions of the same jaw.

Outcome variables

Implant survival

Implant survival was assessed at the 15-year follow-up examination. The implant survival was defined as the implant being in place and stable. The stability of the implant-supported reconstruction and, if necessary, of the implant were assessed by mechanical testing with a hand instrument.

Interproximal marginal bone level

At 5 and 15 years, periapical radiographs were taken using the long-cone paralleling technique with the central beam aiming at the alveolar crest (Updegrave 1968). The radiographs were digitized as jpeg-files and imported into an analysis software (ImageJ, National Institute of Health, Bethesda, MD, USA). The interproximal marginal bone level ($MBL_{interprox}$) was assessed on the mesial and on the distal aspect of each implant by measuring the distance from the implant shoulder to the first visible bone-to-implant contact. The distance between implant threads was used for the calibration of the distances. Mesial and distal $MBL_{interprox}$ values were averaged to one value per implant. The change in $MBL_{interprox}$ from 5-year to 15-year examination was calculated. A positive change of $MBL_{interprox}$ denoted a loss of marginal bone.

Buccal bone and mucosa dimensions

At the 15-year follow-up examination, CBCT imaging was performed with a 3DExam CBCT scanner (KaVo Dental, Biberich, Germany). To allow depicting the soft tissues on the CBCT, a thin layer of light-curing radio-opaque flowable composite was applied on the peri-implant mucosa of the study implants and cured (Benic et al. 2012, Jung et al. 2015). The scans were made using the following technical parameters: 120 kV, 5 mA, 19 mAs, voxel size of 0.125 mm and 360° rotation. Bucco-oral sections perpendicular to the implant central axis were used for CBCT analysis (OsiriX imaging software, Geneva, Switzerland).

The following parameters were assessed at the buccal aspect of each implant:

- Buccal marginal bone level (MBL_{buccal}): apico-coronal distance from the first bone-to-implant contact to the implant shoulder
- Bucco-oral bone thickness measured 1, 2 and 3 mm apical to the implant shoulder (BT_{1mm}, BT_{2mm}, BT_{3mm})
- Marginal mucosa level (MML): apico-coronal distance from the marginal mucosa to the implant shoulder
- Mucosa height (MH): buccal marginal bone level + marginal mucosa level
- Bucco-oral mucosa thickness measured 1 mm apical to the marginal mucosa (MT).

Clinical parameters

At 5 and 15 years, the following variables were assessed:

- Plaque control record (PCR) at 6 sites per implant investigated (O'Leary et al. 1972),
- Bleeding on probing score (BOP) at 6 sites per implant investigated (Ainamo & Bay 1975),
- Probing pocket depth (PPD) to the nearest millimeter at 6 sites per implant investigated.

The six values around each implant for PCR, BOP and PPD were averaged to one value per implant. The 5- to 15-year changes were calculated.

Statistical analysis

The statistical procedure was described in detail in a previous publication (Benic et al. 2009). The estimation of the implant survival rate was based on Kaplan–Meier analysis and a group comparison was made using the log-rank test (R software; R Foundation, Vienna, Austria). Only the cases with both test and control implants were used for the following analysis. For continuous parameters, the data distributions were represented with boxplots and the data were reported by means, standard deviations (SD), medians, 95% confidence intervals (95% CI), and ranges (SPSS software; SPSS Inc., Chicago, IL, USA). The paired t-test was applied to detect differences between the test and the control implants. Results of tests with p-values ≤ 0.05 were considered statistically significant (R software; R Foundation, Vienna, Austria). To control for multiple testing, the Benjamini and Hochberg False Discovery Rate was applied. The power of the comparison between test and control implants had been computed for the patient cohort examined at the 5-year examination. It showed > 95% power for $MBL_{interprox}$.

Results

The results of the assessment at 5 years were published in a previous publication.

Patients and implants

At the 15-year examination 23 out of the 32 invited patients were examined. Sixteen women and 7 men presented with a median age of 56.8 years (range 18.0 - 74.5 years) at implant placement. They had received 23 GBR and 23 control implants. In either group there were 9 maxillary and 14 mandibular implants, and 21 posterior and 2 anterior implants. The distributions of implant lengths and diameters are presented in Table A1. In 18 patients GBR involved grafting with DBBM, alone or in combination with autogenous bone (cohort *DBBM*). In the remaining 5 patients, GBR procedure was executed by grafting with autogenous bone only (cohort *autogenous bone*). The majority of the implants were reconstructed with fixed prostheses: 9 with single-crowns and 29 with splinted reconstructions. The other 8 implants supported removable prostheses. In 22 of 23 patients, the test and the control implant exhibited the same type of reconstruction (Table A1). The follow-up period after implant placement ranged from 172 to 209 months (mean and median 15.2 years).

Implant survival

One GBR implant was lost between 5 and 15 years, rendering a 15-year implant survival rate of 95.6% (95% CI: 87.7%; 100%) for the GBR group. In the control group, two implants were lost and the 15-year survival rate amounted to 94.1% (95% CI: 86.5%; 100%). One control implant was lost 5 months after implant placement. This implant had been loaded only 3 weeks after placement and subsequently became mobile. In another patient, one control implant was not osseointegrated at the time of abutment connection, 6 months after implant placement. The difference in the 15-year survival rate between the groups was not statistically significant ($p = 0.56$).

The cases with lost implants were excluded from the statistical analysis of the following clinical and radiographic parameters. Therefore, 22 cases with 44 implants were included for the analysis.

Interproximal marginal bone level

Radiographic evaluation indicated that all implants were successfully osseointegrated as seen by close bone-to-implant contact at the implant surface from alveolar crest to the apical end.

At the 5-year examination, the mean $MBL_{interprox}$ measured 1.33 ± 0.51 for the GBR implants and 1.60 ± 0.86 for the control implants (Benic et al. 2009) (Table 1). At 15 years, the corresponding values amounted to 1.44 ± 0.84 mm for the GBR group and to 1.69 ± 0.84

mm for the control group. The differences between the groups were not statistically significant (5 years: p = 0.080; 15 years: p = 0.591). At 15 years, there were 5 out of 22 (22.7%) implants with a $MBL_{interprox}$ value > 2 mm in each group. From the 5- to the 15-year examination, the change in mean $MBL_{interprox}$ reached 0.23 ± 0.70 mm for the GBR group and 0.28 ± 0.63 mm for the control group. The values for the two treatment modalities did not significantly differ (p = 696). From 5 to 15 years, there were 3 out of 22 (13.6%) implants with > 1 mm of change in mean $MBL_{interprox}$ in each group. No implant lost > 2 mm of interproximal bone level from 5 to 15 years (Fig. 1).

For the DBBM cohort (n = 17), the 15-year mean $MBL_{interprox}$ amounted to 1.57 ± 0.84 mm for the GBR implants and to 1.76 ± 0.86 mm for the control implants without a statistically significant difference (p = 0.543) (Table 1). The 15-year mean $MBL_{interprox}$ reached > 2 mm in 5 out of 17 (29.4%) GBR and 5 out of 17 (29.4%) control implants. In the DBBM cohort, the change in mean $MBL_{interprox}$ from 5 to 15 years reached 0.35 ± 0.68 mm for the GBR group and 0.28 ± 0.63 mm for the control group. The difference between the GBR and the control implants was not statistically significant (p = 0.853). From 5 to 15 years, 3 out of 17 (17.6%) GBR implants and 1 out of 17 (5.8%) control implants lost > 1 mm of interproximal bone level (Fig. 1).

When considering the patients that received GBR with autogenous bone only (n = 5), the 15-year mean $MBL_{interprox}$ reached 1.01 ± 0.75 mm for the GBR implants and 1.45 ± 0.83 mm for the control implants (Table 1). In this group of the patients, the 5- to 15-year change in mean $MBL_{interprox}$ amounted to -0.18 ± 0.67 mm for the GBR group and to 0.28 ± 0.71 mm for the control group. The differences between the GBR and the control implants did not significantly differ (15-year $MBL_{interprox}$: p = 0.570; 5- to 15-year change of $MBL_{interprox}$: p = 0.570).

Buccal marginal bone level and thickness

Four CBCT were not readable due to beam hardening artifacts caused by prosthetic screws made of gold. Therefore, 18 CBCT data sets were analyzed.

At 15 years, MBL_{buccal} reached 1.98 ± 0.98 mm for the GBR implants and 2.19 ± 1.29 mm for the control implants (Table 1). There were 6 out of 18 (33.3%) GBR implants and 7 out of 18 (38.9%) control implants with a MBL_{buccal} value > 2 mm (Fig. 2). The values of BT_{1mm}, BT_{2mm} and BT_{3mm} at 15 years are presented in Table 1. BT_{1mm} measured 0 mm in 16 out of 18 (88.9%) GBR implants and in 100% of control implants. The number of implants with a BT_{2mm} value of 0 mm was 6 (33.3%) in the GBR group and 7 (38.9%) in the control group. There were no significant differences in MBL_{buccal} and BT between the GBR and the control implants (p > 0.5) (Fig. 3a, 4a).

When analyzing only the cases that received GBR with DBBM, the 15-year MBL_{buccal} amounted to 2.03 ± 0.99 mm for the GBR implants and to 2.39 ± 1.45 mm for the control implants (Table 1, Fig. 3b). The difference between the groups was not statistically significant (p = 0.543). There were 4 out of 13 (30.7%) GBR implants and 5 out of 13 (38.5%) control implants with a MBL_{buccal} value > 2 mm (Fig. 2). In the cohort DBBM, the mean values of BT were higher for the GBR implants than for the control implants (Table 1, Fig. 4b). The differences between the groups were, however, not statistically significant (p > 0.1). BT_{1mm} measured 0 mm in 12 out of 13 (92.3%) GBR implants and in 13 out of 13 (100%) of control implants. There were 4 (30.8%) GBR implants and 6 (46.2%) control implants with a BT_{2mm} value of 0 mm.

In the cohort autogenous bone, at 15 years, MBL_{buccal} reached 1.83 ± 1.07 mm for the GBR implants and 1.63 ± 0.33 mm for the control implants (Table 1, Fig. 3c). The results of BT are presented in Table 1. In this cohort the control implants generally rendered higher mean dimensions of the buccal bone, although there were no statistically significant differences (p > 0.5) (Fig. 4c).

Buccal marginal mucosal level and thickness

At the 15-year follow-up examination, MML measured 1.88 ± 0.83 mm for the GBR group and 1.77 ± 0.86 mm for control group (Table 1, Fig. 3a). All the GBR and the control implants exhibited sub-mucosal positions of the implant shoulder. In terms of MH, GBR implants rendered a mean value of 3.75 ± 1.20 mm and control implants 3.96 ± 1.35 mm. The results of MT amounted to 1.08 ± 0.48 for the GBR group and to 1.21 ± 0.46 mm for the control group. There were no statistically significant differences in MML, MH and MT between the GBR implants and the control implants (p > 0.5).

The analysis of the DBBM cohort rendered mean values in MML of 1.98 ± 0.85 mm for the GBR implants and 1.70 ± 0.86 mm for the control implants (Table 1, Fig. 3b). In this cohort MH measured 3.86 ± 1.31 mm for the GBR implants and 4.09 ± 1.52 mm for the control implants, while MT reached 1.12 ± 0.52 mm for the GBR group and 1.21 ± 0.49 mm for the control group. In the DBBM cohort the differences in MML, MH and MT between the GBR and the control implants were not statistically significant (p > 0.1).

In the autogenous bone cohort, MML reached 1.62 ± 0.79 mm for the GBR implants and 1.96 ± 0.93 mm for the control implants (Table 1, Fig. 3c). The mean value in MH for the GBR group was 3.45 ± 0.88 mm. The corresponding value for the control implants amounted to 3.59 ± 0.75 mm. MT reached 1.01 ± 0.38 mm for the GBR group and 1.24 ± 0.42 mm for the control group. For the autogenous bone cohort, the differences in MML, MH and MT between the GBR implants and the control implants were not statistically significant (p > 0.5).

Clinical parameters

The 15-year results of PCR, BOP, PPD, and 5- to 15-year changes BOP and PPD are presented in Table 2. There were no statistically significant differences in PCR, BOP and PPD between the groups ($p > 0.5$).

At the 15-year follow-up examination, bleeding on probing occurred in totally 32 out of 44 (72.7%) implants. Therefore, according to the specific definition (Sanz et al. 2012), peri-implant mucositis was diagnosed at 17 GBR implants and at 15 control implants.

Discussion

The results of the present long-term clinical study indicate that implants placed simultaneously to GBR with particulate graft and collagen membrane do not differ from implants completely placed into pristine bone with respect to 15-year implant survival and interproximal bone levels. Furthermore, there were no differences between the test and the control implants regarding the buccal bone and mucosa dimensions and the clinical parameters. The majority of the implants at both augmented and control sites exhibited stable interproximal bone levels from 5 years to 15 years after implant placement.

The data for **implant survival and interproximal bone levels** from the present investigation without differences between GBR and control implants confirm the findings of previous clinical trials with internal control. In fact, several controlled trials with follow-up durations up to 5 years and one clinical study with a mean observation time of 12.5 years did not reveal differences in implant survival and interproximal bone level between implants placed into augmented sites and those placed into native bone (Benic et al. 2009, Jung et al. 2013, Mayfield et al. 1998, Zumstein et al. 2012). Moreover, the interproximal bone levels for the control and the GBR group in the present study are in agreement with the ones observed in long-term studies documenting the outcome of implants placed in native bone under standard conditions (Adell et al. 1981, Jemt & Johansson 2006, Ekelund et al. 2003, Jung et al. 2013).

To our knowledge, the present investigation is the first one that compared **buccal bone** and mucosa dimensions at implant sites augmented with GBR to control sites without GBR. At the 15-year CBCT examination, there were no significant differences between the GBR and the control implants. As far as the dimension of the buccal bone plate is concerned, overall, the mean distance between the implant shoulder and the buccal first bone-to-implant-contact was approximately 2 mm. Thirteen out 36 (36%) of the implants exhibited buccal first-bone-to-implant contact > 2 mm apical to the implant shoulder.

Several clinical studies measured the dimensions of the buccal bone at implants treated with GBR by means of CBCT. Some of these studies assessed the buccal bone at implants placed with GBR **immediately after tooth extraction** and combined with GBR in the anterior jaw regions and found pronounced resorption of the buccal bone plate (Benic et al. 2012, Kuchler et al. 2016, Miyamoto & Obama 2011). In one study, implants placed immediately into extraction sockets were radiographically evaluated after 7 years (Benic et al. 2012). At implant placement, infrabony defects and dehiscences were grafted with DBBM and covered with collagen membranes (CM) without over-augmenting the remaining buccal bone plate. At the 7-year follow-up, in one-third of the sites almost no buccal bone was radiographically detected, whereas in the other two-thirds, the buccal bone plate covered the

entire rough implant surface. The mucosal margin was located 1 mm more apically within the group of implants without radiographically detectable buccal bone. The findings regarding the buccal bone plate from this study were confirmed by a 10-year CBCT investigation, in which the same treatment protocol was applied (Kuchler et al. 2016). In fact, the patients examined in these two studies were originally treated within one multicenter clinical project (Lang et al. 2007). After 10 years of function, one-fourth of the sites showed almost no buccal bone on the CBCTs (Kuchler et al. 2016). The pronounced resorption of the buccal plate observed in the investigations of implants placed into fresh extraction sockets can be explained by the post-extractive resorption of the alveolar ridge.

In contrast, recent CBCT trials of implants placed and treated with GBR **at least 6 weeks after tooth extraction** found well maintained levels of the augmented buccal bone after 5-9 years (Jung et al. 2015, Buser et al. 2013). In a randomized clinical trial, peri-implant defects augmented with DBBM and CM were clinically assessed at 6-month re-entry and visualized with CBCT after 5 years (Jung et al. 2009, Jung et al. 2015). At 5 years, the mean distance between the implant shoulder and the first bone-to-implant-contact was 2.2 mm. It has, however, to be taken into account that the used soft tissue level implants had a machined neck of 1.8 mm. The average thickness of the buccal bone measured at the levels 1 to 5 mm apical to the most coronal level of the alveolar crest reached 2 to 3 mm. Due to the different locations of the regions-of-interest, the results in bone thickness from this study cannot be compared with the data found in the present trial. To allow standardized measurements, in the present study the bone thickness was assessed at 1 to 3 mm apical to the implant shoulder. A clinical CBCT cross-sectional investigation of buccal bone reported outcomes after 5-9 years of prosthetic function (Buser et al. 2013). In this study implants were placed in the anterior jaw regions 6-8 weeks after tooth extraction and combined with simultaneous contour augmentation by means of GBR. The augmentation procedure involved grafting with particulate autogenous bone and DBBM, and coverage of the augmented sites with CM. The CBCT examination of the facial bone wall revealed a mean thickness of 1.6 and 2.2 mm in the regions-of-interest 2 mm and 4 mm apical to the shoulder of the soft tissue level implants, respectively. The frequency analysis showed that at the 2-mm level, representing roughly the beginning of the structured implant surface, 8 of 41 implants showed no facial bone. At the 4- and 6-mm levels, no facial bone could be detected at two implants.

One of the **shortcomings** of the present study is represented by the fact that no baseline assessments had been performed at implant placement or insertion of the reconstruction. Therefore, the buccal bone level at 15 years and not the 15-year change in bone level was measured. Another shortcoming of this trial is the high drop out rate at 15 years resulting in a relatively low sample size. This fact and the variability in the grafting

materials used for GBR are considerable limitations, which have to be taken into account when interpreting the findings of the present study.

Another methodological shortcoming of this investigation is that dental implants and other highly X-ray absorbing objects cause artifacts within **CBCT** images (Benic et al. 2013, Draenert et al. 2007, Sancho-Puchades et al. 2015, Schulze et al. 2010). It is, therefore, controversial whether the peri-implant tissue can accurately be assessed by this technique. A recent review of the literature on digital methods for the assessment of outcomes in implant dentistry concluded that CBCT has the potential to allow accurate assessment of peri-implant bone plates with a thickness > 0.5 mm (Benic et al. 2015). In other words, in the present trial the presence of thin buccal bone plates might have been underestimated. Four CBCT images had to be excluded from the assessment due to the pronounced presence of artifacts that were induced by gold abutment screws. The quality of the remaining CBCT images representing implants with titanium abutment screws was rated adequate for the assessment of the buccal tissues.

It is worth noting that in cases in which GBR involved grafting with DBBM, GBR implants achieved approximately 0.3-0.4 mm higher mean and median values in buccal bone level, bone thickness and mucosal level in comparison to the implants placed into native bone without GBR. In contrast, when GBR was performed by grafting with autogenous bone without DBBM, implants rendered less favorable results in buccal bone and mucosa dimensions than the control implants. The differences between the GBR and the control implants were, however, not statistically significant. Due to the low sample size, the differences in the buccal bone dimensions found for GBR with DBBM and autogenous bone need to be considered with caution.

The findings of the present trial are clinically relevant. First, they add additional comparative evidence on the long-term performance of implants placed into augmented sites and those placed into pristine bone without GBR. Second, they provide information on the hard and soft tissue dimensions in the regions treated with GBR. Future long-term controlled clinical studies with baseline and follow-up measurements are required to confirm the findings of the present trial. The stability of the hard tissue augmented by using different biomaterials and techniques needs to be further investigated.

Finally, it is important to emphasize that in the absence of clinical symptoms or certain postoperative complications, there is no indication for follow-up imaging of dental implants by means of CBCT. Due to the higher radiation burden compared with the two-dimensional radiography, CBCT imaging cannot be justified where there is no direct benefit to the patient, except as part of ethically approved clinical research (Harris et al. 2012, Dula et al. 2015).

Conclusions

Within the limitations of the present long-term observation study, it can be concluded that:

- Implants placed simultaneously to GBR using particulate DBBM and/or autogenous bone in combination with a native collagen membrane did not significantly differ from implants completely placed into pristine bone with respect to 15-year implant survival, interproximal bone levels, and dimensions of the buccal bone and mucosa.
- The machined-surface implants placed both into native bone and sites augmented by GBR exhibited stable interproximal bone levels over a 15-year period.
- GBR involving grafting with DBBM lead to approximately 0.3-0.4 mm higher mean and median values in buccal bone level, bone thickness and mucosal level in comparison to control implants placed into native bone without GBR. In contrast, GBR performed by grafting with autogenous bone without DBBM rendered less favorable results in buccal bone and mucosa dimensions than implant placement without GBR.

Acknowledgements

The investigators gratefully acknowledge Dr. Tobias Waller and Gisela Müller (Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine, University of Zurich, Switzerland). This study was supported by the Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine, University of Zurich, Switzerland and by a research grant from Geistlich Pharma AG, Wolhusen, Switzerland.

Table legend

Table 1. Results of the conventional radiographic and CBCT measurements

Table 2. Results of the clinical measurements

Table A1. Distributions of implant lengths, implant diameters, and reconstruction types presented as absolute values

Figure legend

Figure 1. Frequency distribution of the change in mean interproximal marginal bone level from the 5-year to the 15-year examination at control sites, sites in which GBR involved grafting with DBBM (GBR DBBM), and sites in which GBR involved grafting with autogenous bone only (GBR AB).

Figure 2. Frequency distribution of the buccal marginal bone level at the 15-year examination at control sites, sites in which GBR involved grafting with DBBM (GBR DBBM), and sites in which GBR involved grafting with autogenous bone only (GBR AB).

Figure 3. Box plots representing the buccal marginal bone level (MBL_{buccal}) and the buccal marginal mucosa level (MML_{buccal}) relative to the implant shoulder at the 15-year examination (a) in the entire study cohort, (b) in patients in which GBR involved grafting with DBBM (GBR DBBM) and (c) in patients in which GBR involved grafting with autogenous bone only (GBR AB). ° and * in the figures represent the outliers.

Figure 4. Box plots representing the bucco-oral bone thickness measured 1, 2 and 3 mm apical to the implant shoulder at the 15-year examination (a) in the entire study cohort, (b) in patients in which GBR involved grafting with DBBM (GBR DBBM), and (c) in patients in which GBR involved grafting with autogenous bone only (GBR AB). ° and * in the figures represent the outliers.

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				GBR					Control					
Cohort	Parameter	Time	n	Mean ± SD	Median	95% CI	Range		Mean ± SD	Median	95% CI	Range		P-value*
(a) Total														
	Mean $MBL_{interprox}$	5y	32	1.33 ± 0.51	1.34	1.14-1.51	0-2.36		1.60 ± 0.86	1.62	1.29-1.91	0.07-3.64		0.080
	Mean $MBL_{interprox}$	15y	22	1.44 ± 0.84	1.36	1.07-1.82	0-2.87		1.69 ± 0.84	1.48	1.32-2.06	0.24-3.62		0.591
	Change of mean $MBL_{interprox}$	5y-15y	22	0.23 ± 0.70	0.02	-0.07-0.54	-1.11-1.47		0.28 ± 0.63	0.36	-0.01-0.57	-1.37-1.24		0.696
	MBL_{buccal}	15y	18	1.98 ± 0.98	1.86	1.49-2.46	0.18-4.70		2.19 ± 1.29	1.61	1.57-2.81	1.14-5.52		0.636
	BT_{1mm}	15y	18	0.12 ± 0.37	0	-0.06-0.30	0-1.44		0 ± 0	0	0-0	0-0		0.591
	BT_{2mm}	15y	18	0.82 ± 0.99	0.42	0.32-1.31	0-3.44		0.79 ± 0.75	0.77	0.43-1.16	0-2.25		0.748
	BT_{3mm}	15y	18	1.41 ± 1.22	1.13	0.81-2.02	0-4.43		1.28 ± 1.07	1.34	0.76-1.79	0-3.55		0.636
	MML	15y	18	1.88 ± 0.83	2.08	1.45-2.30	0.39-2.91		1.77 ± 0.86	1.76	1.35-2.18	0.78-3.94		0.636
	MH	15y	18	3.75 ± 1.20	3.50	3.15-4.34	1.53-6.13		3.96 ± 1.35	3.45	3.31-4.61	2.31-7.05		0.741
	MT	15y	18	1.08 ± 0.48	1.05	0.84-1.33	0.43-2.07		1.21 ± 0.46	1.25	0.99-1.43	0.45-1.93		0.636
(b) DBBM														
	Mean $MBL_{interprox}$	15y	17	1.57 ± 0.84	1.40	1.13-2.01	0-2.87		1.76 ± 0.86	1.56	1.32-2.20	0.82-3.62		0.543
	Change of mean $MBL_{interprox}$	5y-15y	17	0.35 ± 0.68	0.42	0.01-0.70	-0.64-1.47		0.28 ± 0.63	0.36	-0.05-0.62	-1.37-1.24		0.853
	MBL_{buccal}	15y	13	2.03 ± 0.99	1.86	1.44-2.63	0.79-4.70		2.39 ± 1.45	1.70	1.55-3.23	1.14-5.52		0.543
	BT_{1mm}	15y	13	0.05 ± 0.19	0	-0.06-0.17	0-0.70		0 ± 0	0	0-0	0-0		0.543
	BT_{2mm}	15y	13	0.91 ± 1.06	0.84	0.27-1.55	0-3.44		0.66 ± 0.73	0.50	0.23-1.08	0-2.25		0.393
	BT_{3mm}	15y	13	1.60 ± 1.33	1.27	0.79-2.40	0-4.43		1.14 ± 1.17	0.78	0.47-1.82	0-3.55		0.393
	MML	15y	13	1.98 ± 0.85	2.20	1.44-2.52	0.39-2.91		1.70 ± 0.86	1.56	1.20-2.20	0.78-3.94		0.393
	MH	15y	13	3.86 ± 1.31	3.57	3.07-4.65	1.53-6.13		4.09 ± 1.52	3.54	3.21-4.96	2.31-7.05		0.798
	MT	15y	13	1.12 ± 0.52	1.05	0.78-1.45	0.43-2.07		1.21 ± 0.49	1.28	0.92-1.49	0.45-1.93		0.707
(c) Autogenous bone														
	Mean $MBL_{interprox}$	15y	5	1.01 ± 0.75	1.32	0.08-1.94	0-1.87		1.45 ± 0.83	1.38	0.42-2.48	0.24-2.53		0.570
	Change of mean $MBL_{interprox}$	5y-15y	5	-0.18 ± 0.67	-0.22	-1.01-0.65	-1.11-0.77		0.28 ± 0.71	0.04	-0.60-1.16	-0.54-1.22		0.570
	MBL_{buccal}	15y	5	1.83 ± 1.07	1.87	0.50-3.16	0.18-3.08		1.63 ± 0.33	1.52	1.22-2.04	1.39-2.20		0.868
	BT_{1mm}	15y	5	0.29 ± 0.64	0	-0.51-1.09	0-1.44		0 ± 0	0	0-0	0-0		0.654
	BT_{2mm}	15y	5	0.58 ± 0.84	0.39	-0.47-1.62	0-2.04		1.17 ± 0.76	1.40	0.23-2.11	0-2.05		0.570
	BT_{3mm}	15y	5	0.94 ± 0.83	0.75	-0.09-1.97	0-2.25		1.66 ± 0.69	2.08	0.80-2.51	0.54-2.12		0.570
	MML	15y	5	1.62 ± 0.79	1.36	0.65-2.60	0.62-2.48		1.96 ± 0.93	1.76	0.80-3.12	0.83-3.42		0.654
	MH	15y	5	3.45 ± 0.88	3.23	2.37-4.54	2.55-4.83		3.59 ± 0.75	3.28	2.66-4.52	3.03-4.87		0.837
	MT	15y	5	1.01 ± 0.38	1.14	0.54-1.48	0.58-1.49		1.24 ± 0.42	1.11	0.72-1.75	0.71-1.67		0.687

DBBM, deproteinized bovine bone mineral; MBL, marginal bone level; BTxmm, bone thickness measured xmm apical to the implant shoulder; MML, marginal mucosa level; MH, mucosa height; MT, mucosa thickness; y, years; GBR, guided bone regeneration; n, number; SD, standard deviation; 95% CI, 95% confidence interval; *, results of paired t-test corrected for multiple testing with Benjamini & Hochberg

Table 1

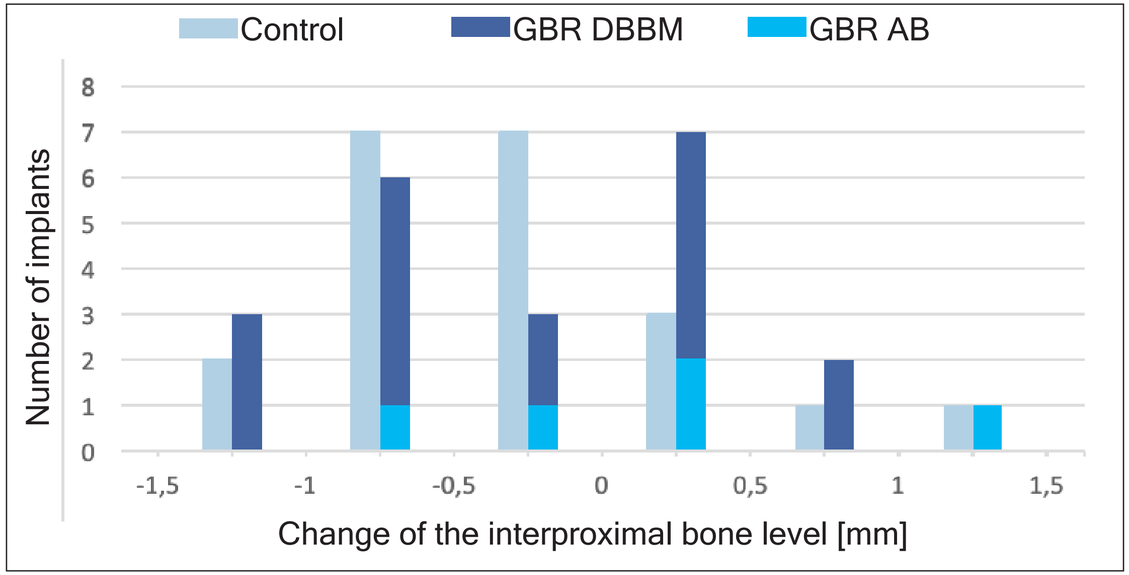
					GBR					Control					
Cohort	Parameter	Time	Unit	n	Mean ± SD	Median	95% CI	Range		Mean ± SD	Median	95% CI	Range		P-value*
(a) Total															
	PCR	15y	%	22	36.3 ± 30.7	33.0	22.7-49.9	0-100		30.4 ± 36.2	17.0	14.3-46.4	0-100		0.591
	BOP	15y	%	22	46.2 ± 27.7	50.0	33.9-58.5	0-100		38.3 ± 28.8	30.0	25.4-51.1	0-100		0.591
	Mean PPD	15y	mm	22	3.12 ± 0.71	3.00	2.80-3.43	2.00-5.17		3.05 ± 0.67	3.00	2.75-3.35	2.00-4.67		0.696
(b) DBBM															
	PCR	15y	%	18	36.1 ± 30.2	33.0	20.6-51.7	0-100		32.4 ± 35.0	17.0	14.4-50.4	0-100		0.689
	BOP	15y	%	18	46.1 ± 28.1	50.0	31.6-60.5	0-100		35.8 ± 25.8	30.0	22.5-49.0	0-83.0		0.393
	Mean PPD	15y	mm	18	3.04 ± 0.73	3.00	2.66-3.41	2.00-5.17		3.06 ± 0.74	3.00	2.68-3.44	2.00-4.67		0.853
(c) Autogenous bone															
	PCR	15y	%	5	36.8 ± 36.0	17.0	-7.9-81.5	0-83.0		23.4 ± 43.4	0	-30.6-77.4	0-100		0.654
	BOP	15y	%	5	46.8 ± 29.6	50.0	10.0-83.6	17.0-83.0		46.8 ± 39.8	50.0	-2.6-96.2	0-100		1.000
	Mean PPD	15y	mm	5	3.39 ± 0.65	3.17	2.58-4.20	2.83-4.30		2.99 ± 0.42	3.00	2.48-3.51	2.50-3.50		0.654

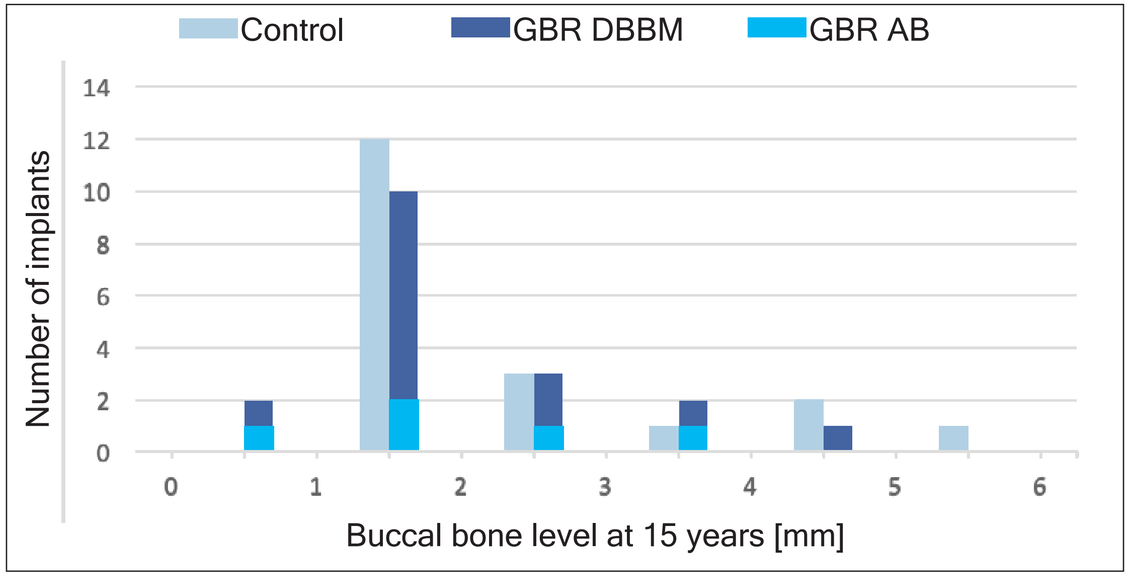
DBBM, deproteinized bovine bone mineral; PCR, plaque control record; BOP, bleeding on probing; PPD, probing pocket depth; y, years; GBR, guided bone regeneration; n, number; SD, standard deviation; 95% CI, 95% confidence interval; *, results of paired t-test corrected for multiple testing with Benjamini & Hochberg

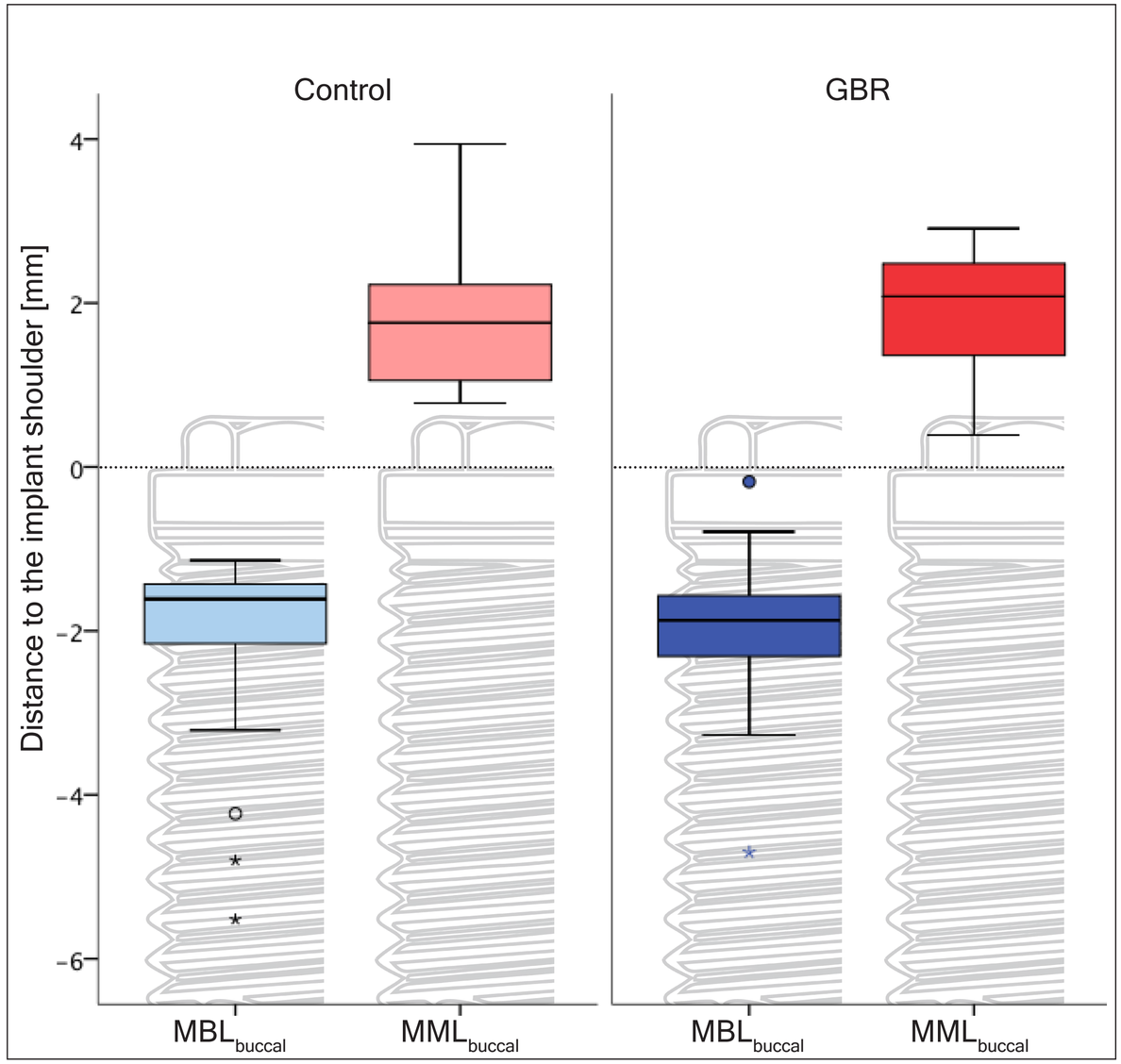
Table 2

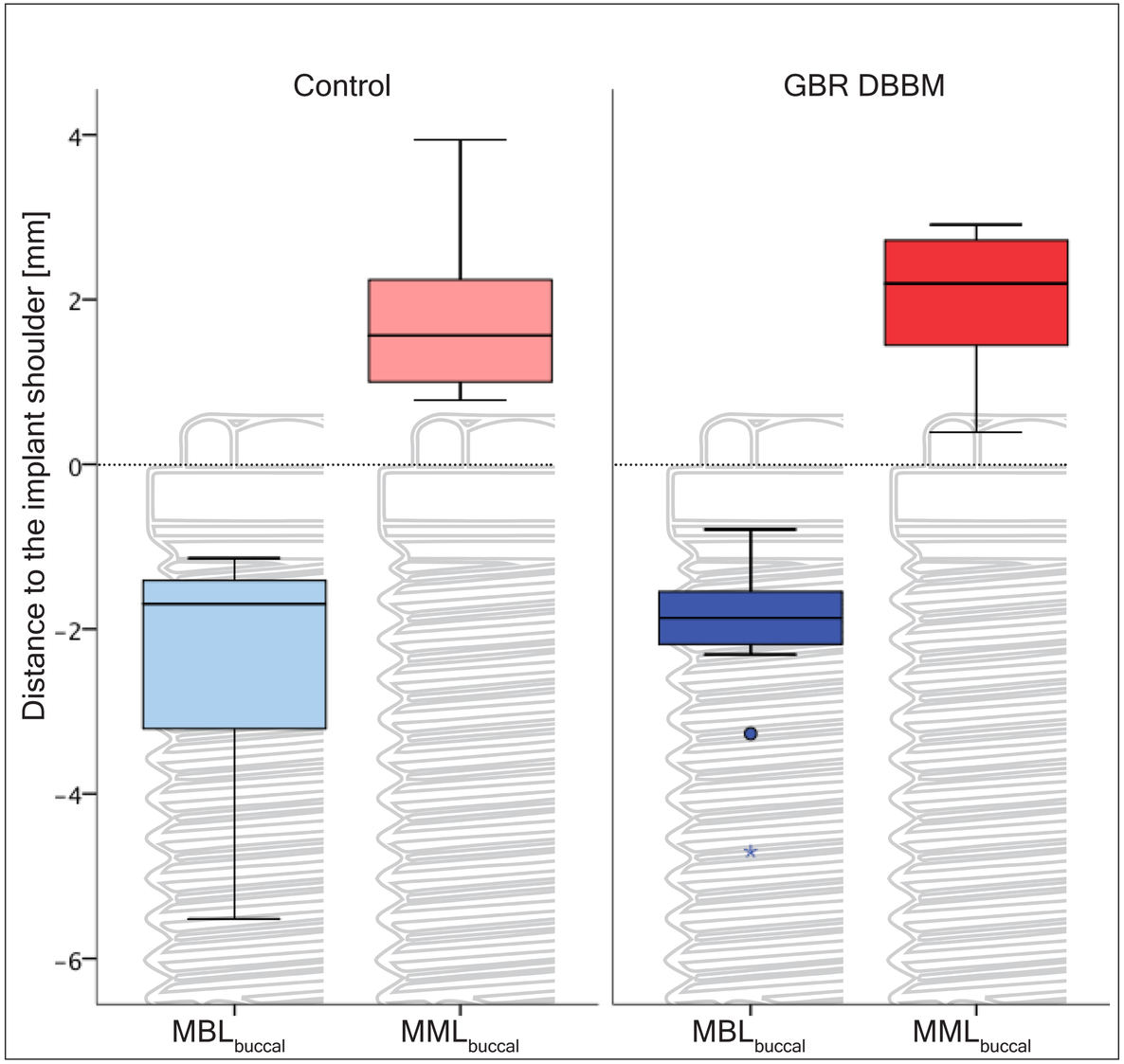
		GBR (n = 23)	Control (n= 23)
Implant length (mm)			
	7	1	1
	8.5	4	5
	10	4	7
	11.5	7	5
	13	7	5
Implant diameter (mm)			
	3.3	1	1
	3.75-4.0	18	17
	5.0	4	5
Reconstruction type			
	Fixed single	4	5
	Fixed splinted	15	14
	Removable single	0	0
	Removable splinted	4	4
GBR, guided bone regeneration; n, number			

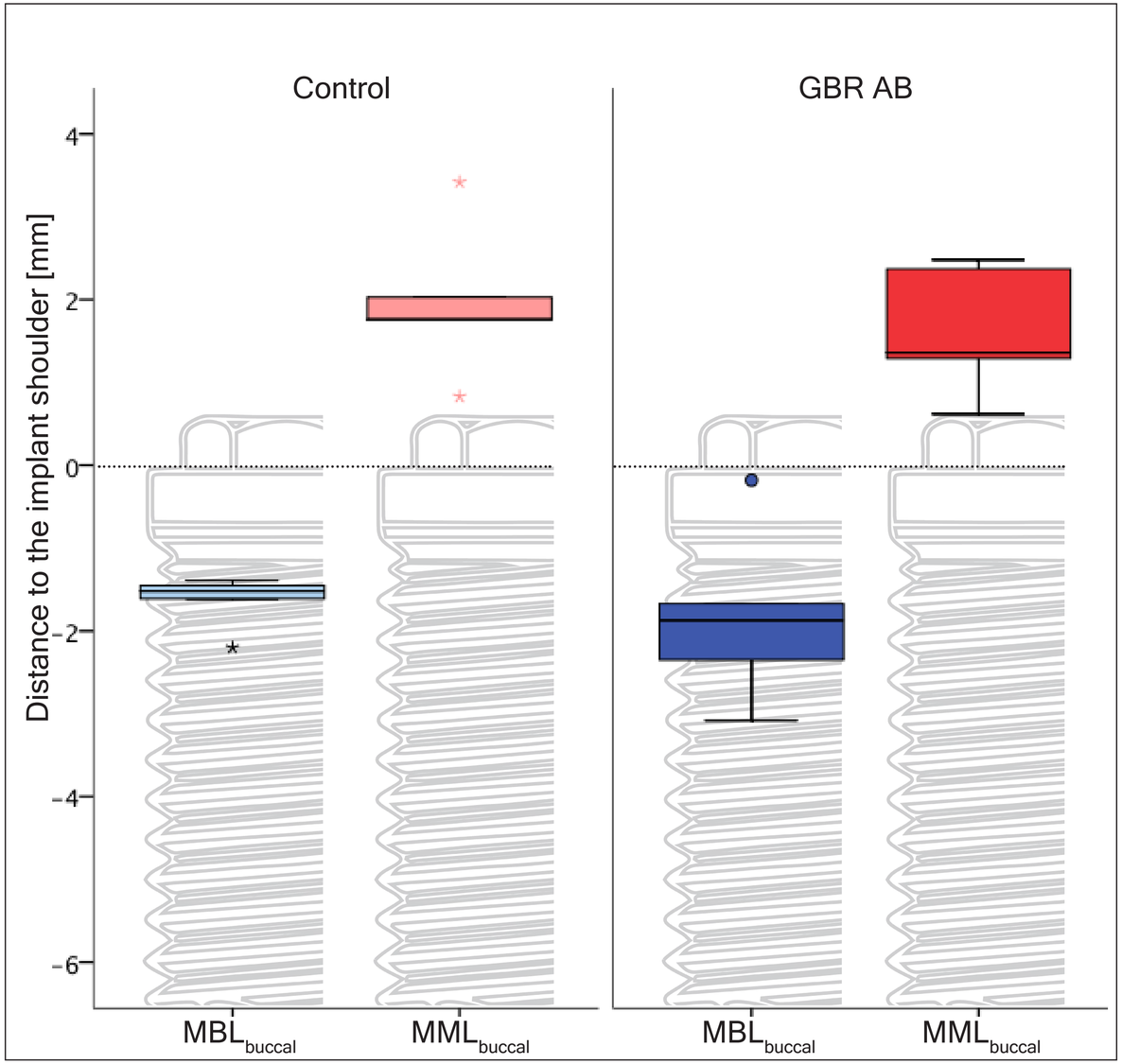
Table A1

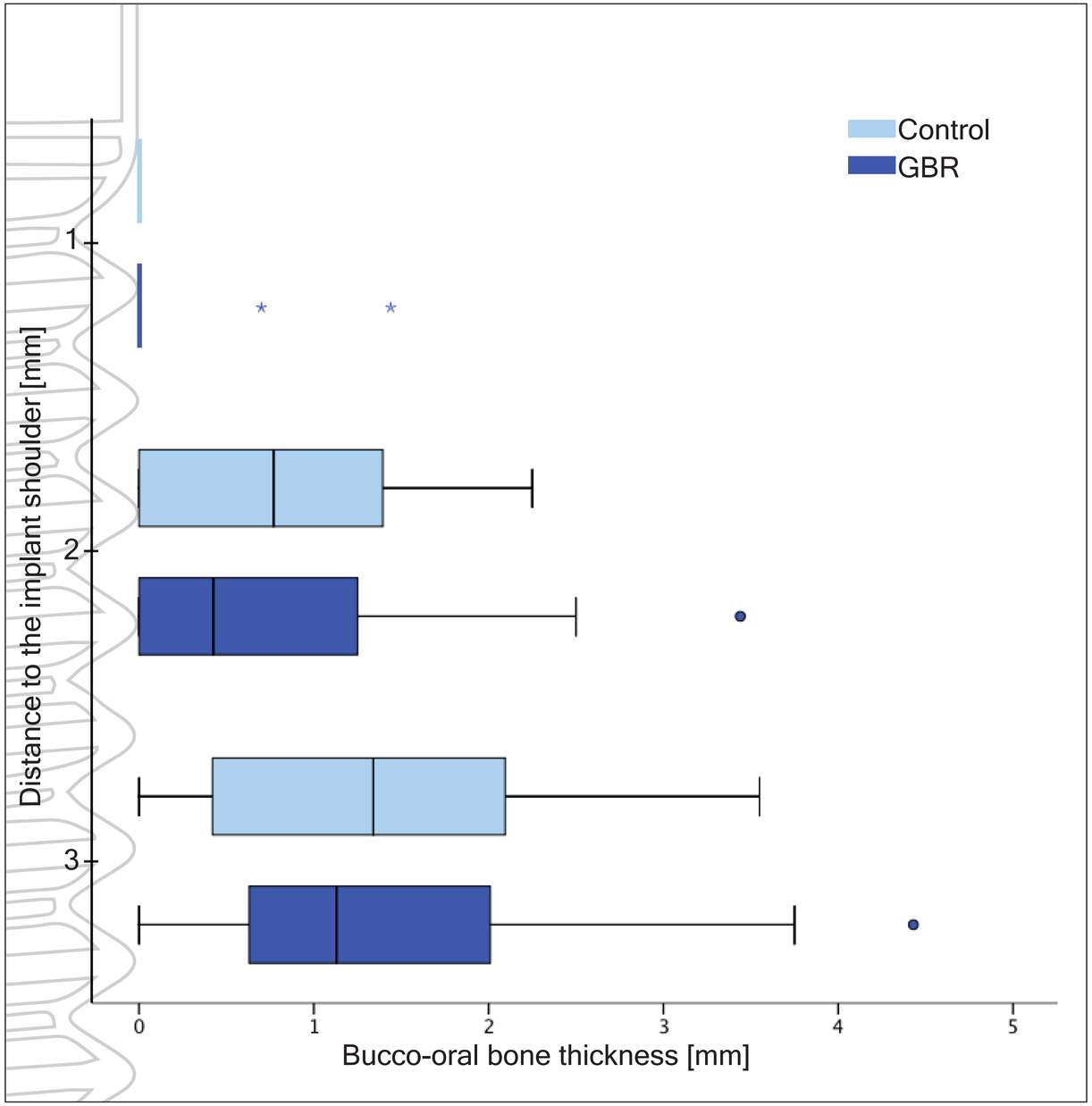

Control
GBR DBBM
GBR AB
Number of implants
8
7
6
5
4
3
2
1
0
-1,5
-1
-0,5
0
0,5
1
1,5
Change of the interproximal bone level [mm]

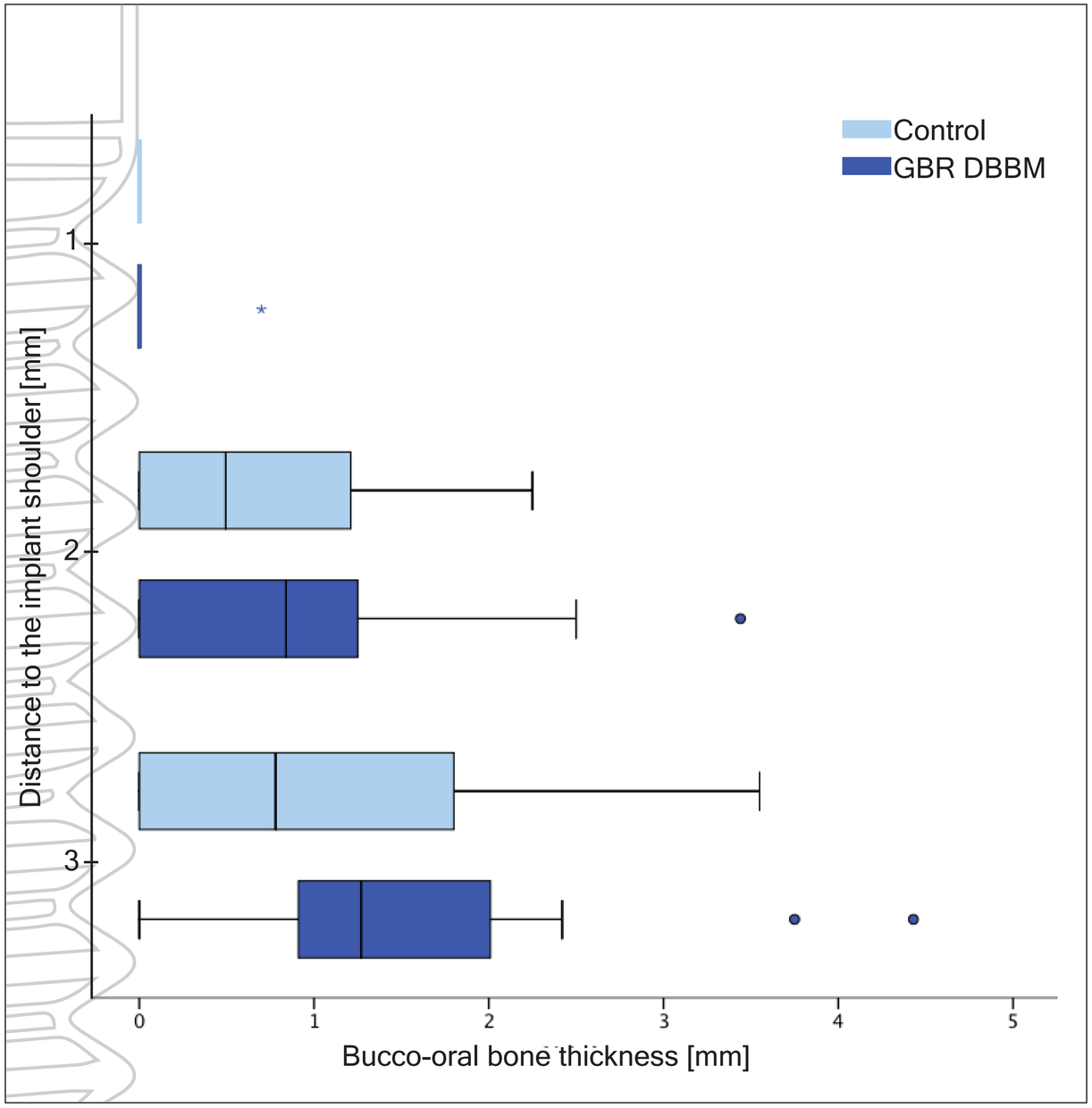

Control
GBR DBBM
GBR AB
Number of implants
14
12
10
8
6
4
2
0
0
1
2
3
4
5
6
Buccal bone level at 15 years [mm]

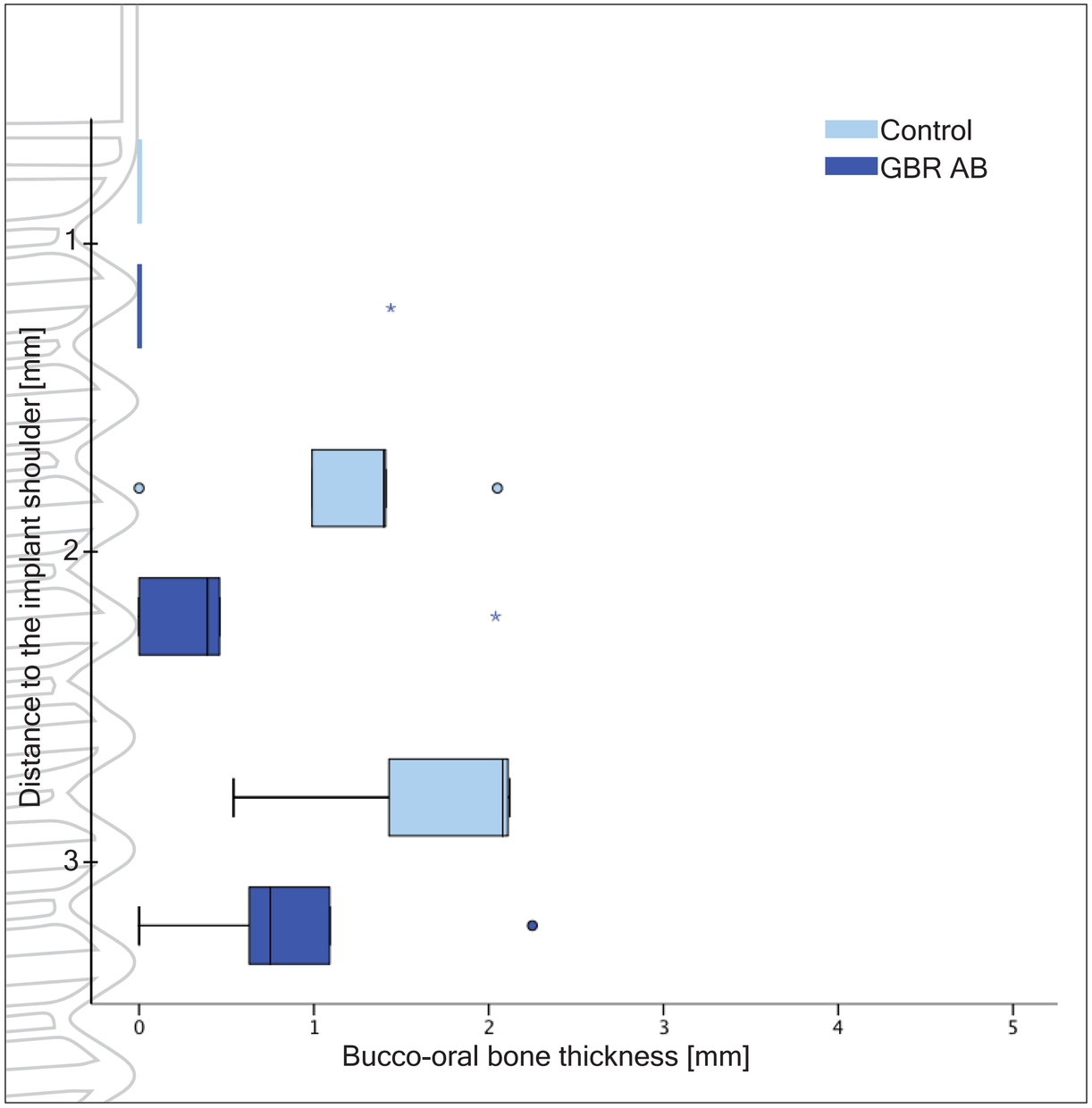

Control
GBR
Distance to the implant shoulder [mm]
4
2
0
-2
-4
-6
MBL buccal
MML buccal
MBL buccal
MML buccal


Control
GBR DBBM
Distance to the implant shoulder [mm]
4
2
0
-2
-4
-6
MBL buccal
MML buccal
MBL buccal
MML buccal


Control
GBR AB
Distance to the implant shoulder [mm]
4
2
0
-2
-4
-6
MBL buccal
MML buccal
MBL buccal
MML buccal


Control
GBR
Distance to the implant shoulder [mm]
1
2
3
0
1
2
3
4
5
Bucco-oral bone thickness [mm]


Control
GBR DBBM
Distance to the implant shoulder [mm]
1
2
3
0
1
2
3
4
5
Bucco-oral bone thickness [mm]


Control
GBR AB
Distance to the implant shoulder [mm]
1
2
3
0
1
2
3
4
5
Bucco-oral bone thickness [mm]